|  | Application No.                                   | Applicant(s)                |
|--|---|-----------------------------|
| Notice of Allowability   | 10/619,910  | NISHIMURA ET AL.            |
|  | Examiner  | Art Unit                    |
|  | Chih Min Kom                                      | 1656                        |
|  | Chih-Min Kam                                      | 1656                        |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. |   |                             |
| 1. This communication is responsive to 9/23/05.  |   |                             |
| 2. The allowed claim(s) is/are <u>15-22,24,35 and 36</u> .   |   |                             |
| 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) □ Some* c) □ None of the:  |   |                             |
| <ol> <li>Certified copies of the priority documents have been received.</li> </ol>   |   |                             |
| 2.  Certified copies of the priority documents have been received in Application No. <u>09/439,779</u> .   |   |                             |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the   |   |                             |
| International Bureau (PCT Rule 17.2(a)).   |   |                             |
| * Certified copies not received:   |   |                             |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.   |   |                             |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.   |   |                             |
| 5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  |   |                             |
| (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached   |   |                             |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date   |   |                             |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date   |   |                             |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).  |   |                             |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  |   |                             |
|  |   |                             |
| ·  |   |                             |
| Attachment(s)  |   |                             |
| 1. Notice of References Cited (PTO-892)  | 5. Notice of Informal Pa                          | atent Application (PTO-152) |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948)   | 6. Interview Summary                              | (PTO-413),                  |
| 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08 Paper No./Mail Date  | Paper No./Mail Date<br>B), 7. ⊠ Examiner's Amendm | e<br>nent/Comment           |
| 4. Examiner's Comment Regarding Requirement for Deposit  | 8. X Examiner's Stateme                           | nt of Reasons for Allowance |
| of Biological Material   | 9.  | ,                           |
|  |   |                             |
| ,  |   |                             |

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#### **DETAILED ACTION**

## Status of the Claims

1. Claims 15-22, 24, 35 and 36 are pending.

Applicant's amendment filed September 23, 2005 is acknowledged, and applicants' response has been fully considered. Claims 15, 18, 20 and 21 have been amended, claims 12-14 and 25-34 have been cancelled, and a new claim 36 has been added. Therefore, claims 15-22, 24, 35 and 36 are examined.

#### Withdrawn Claim Objection

2. The previous objection to claims 15, 18, 20 and 21, is withdrawn in view of applicant's amendment to the claim filed September 23, 2005.

## Withdrawn Claim Rejections - 35 USC § 102

- 3. The previous rejection of claims 25-27, 29, 32 and 34 under 35 U.S.C. 102(b) as anticipated by Oppermann *et al.* (WO89/09788), is withdrawn in view of applicant's cancellation of the claim in the amendment filed September 23, 2005.
- 4. The previous rejection of claims 25-32 and 34 under 35 U.S.C. 102(e) as anticipated by Rueger *et al.* (U.S. Patent 6,281,195), is withdrawn in view of applicant's cancellation of the claim in the amendment filed September 23, 2005.

#### Withdrawn Claim Rejections - 35 USC § 103

3. The previous rejection of claims 15-17, 19, 22, 24-27, 29 and 32-34 under 35
U.S.C. 103(a) as being unpatentable over Oppermann *et al.* (WO89/09788) in view of Lipton
(U.S. Patent 5,028,592), is withdrawn in view of applicant's amendment to the claim, applicant's

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cancellation of the claim, applicant's response at page 6 in the amendment filed September 23, 2005.

# Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

## **Examiner's Amendment to the Specification:**

Please replace the paragraph at page 1, line 4 with the following paragraph:

This application is a divisional of U.S. Application 09/439,779, filed November 12, 1999, now U.S. Patent 6,617,307, which claims the foreign priority of Japanese Application HEI 10-322075 filed on November 12, 1998, whose priority is claimed under 35 USC § 119, the disclosure of which is incorporated by reference in its entirety.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention. Oppermann *et al*. (WO89/09788) teach a synthetic osteogenic protein comprising an amino acid sequence of OP1 (102 amino acid residues), which contains the amino acid sequence of SEQ ID NO:11 at residues 57-76, and can induce endochondral bone formation and bone marrow differentiation at the locus of the implant. However, the reference does not teach or suggest an isolated peptide consisting of SEQ ID NO:11 and an osteogenetic accelerator comprising the peptide attached to a biocompatible carrier. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CYK

Patent Examiner

**CMK** 

October 6, 2005

KATHLEEN M. KERR, PH.D. SUPERVISORY PATENT EXAMINED